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09/934,088	08/20/2001	Roberto A. Gaxiola	883933.0067	7374

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EXAMINER
MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
1638	4

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/934,088	GAXIOLA, ROBERTO A.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-83* is/are pending in the application.

4a) Of the above claim(s) *46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-45 and 47-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4 & 5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group IV, claims 58 and 60-76, in Paper No. 9, received 02 July 2003, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). During the course of examination, it was determined that it would not impose an undue burden to also examine claims 33-45, 47-57, 59, and 77-83. Groups II, III, and V have therefore been rejoined with Group I. The restriction of Group IV, claim 46, is deemed proper and is made FINAL. Non-elected claim 46 is withdrawn from consideration.

Specification

2. There are numerous, incorrect references to the figures throughout the specification. For example, paragraph 0068 starts with an explanation of Figure 5. However, the paragraph then appears to refer Figure 3, while discussing the same data. Paragraph 0072 incorrectly refers to Figure 1 as showing a Western blot. Other incorrect references to the figures also occur. Correction/clarification is required. New matter must be avoided.

3. The first sentence of paragraph 0065 appears to be missing text. Correction/clarification is required. New matter must be avoided.

Claim Objections

4. Claims 40, 58, 71, and 73 are objected to for the following reasons:

Claim 40 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 40 has the same limitations as claim 39.

Claims 58, 71, and 73 are objected to because of the following informalities:

In claim 58, the article, --an-- should be inserted in line 4 before "exogenous."

In claims 71 and 73: the term "*Nicotinia*" is misspelled. Appropriate correction is required.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

5. Claims 38, 43, 44, 49, 51, 55, 56, 57, 77, and 78 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 2, 5, 6, 7, 11, 12, 13, 21, 21, 24, 28, 29, 39, 40, 43, 54 of copending Application No. 09/834,998 ('998). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Instant claim 38 is drawn to a transgenic plants comprising a nucleotide sequence comprising an exogenous gene encoding AVP1 or a homolog thereof, and dependent claims 43 and 44 limit claim 38 by requiring the AVP1 gene to be operably linked to a regulatory element comprising a double tandem enhancer of a 35S CaMV promoter, or by requiring the AVP1 gene or homolog to be derived from a wild type plant. Claims 2, 5, and 6 of co-pending application '998 also drawn to the same products. The claims of '998 indicate that the plants are salt tolerant, whereas the instant claim 38 indicates that the plant is resistant to any externally imposed stress. However, the claimed products are the same. Therefore, the property of salt tolerance is inherent to the instantly claimed plants, and the property of having resistance to externally imposed stresses is inherent to the plants of '998. The product of instant claims 49, 51, and 55-57 are the same as claims 1, 22, 24, 28, 29 of '998, and inherently have the same properties. The transgenic plants of instant claims 77 and 78 are also the same as those of claims 1 and 2 and '998, and therefore inherently have the same properties of salt tolerance and an enhanced capacity to retain solute species in a vacuole.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claims 33-45, 47-57, 68, 69, and 75-79 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-76 of copending Application No. 09/834,998 ('998). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the two applications encompass the same plants, and methods that comprise the same steps. Claim 33 of the instant application is directed to transgenic plants that are resistant to the effects of any and all externally imposed stresses, wherein the plant comprises a nucleotide sequence comprising an exogenous tonoplast pyrophosphatase driven H+ pump gene linked to one or more regulatory elements that alter the expression of vacuolar pyrophosphatase. Dependent claims 34-37 limit the stress to water deficit and exposure to chilling temperatures, and claims 38-45 limit the exogenous nucleic acid to be the AVP1 gene or homolog thereof, and the type of regulatory element present. Claims 47 and 48 are drawn towards seed and progeny of the plant of claim 33. Claims 49-57 are drawn to transgenic plants or cells comprising exogenous nucleic acid that alters the expression of vacuolar pyrophosphatase, but places no limitation on the phenotype of the plants or cells. Instant claims 77-79 are drawn to transgenic plants with enhanced capacity to retain solute species in a vacuole of a plant, wherein the plant is transformed with an exogenous nucleic acid that alters expression of vacuolar pyrophosphatase. Claims 1-29 of co-pending application '998 are drawn towards transgenic plants that are tolerant to any salt, comprising one or more plant cells transformed with exogenous nucleic acid that alters expression of vacuolar pyrophosphatase. The instantly claimed transgenic plants and cells comprise the same exogenous nucleic acid as the claimed plants and cells of '998. The property of having tolerance to a salt is inherent to the instantly claimed products.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 33-45, 47, 48, 51-57, 68, 69, and 75-79 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 13, 28, 42, 48, 61, and 74 of copending Application No. 10/344,658 ('658). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The instant claims and those of the co-pending application are drawn to transgenic plants and cells that comprise nucleic acid comprising an exogenous vacuolar pyrophosphatase gene. The properties of having increased meristematic activity or competence, increased biomass, thicker stem structure, increased root structure, increased shoot regeneration capacity, increased root regeneration capacity, resistance to externally imposed stress, increased seed production, and enhanced capacity to retain solute species in a vacuole are inherent to the instantly claimed products and those of '658.

8. Claims 33-45, 47, 48, 51-57, 68, 69, and 75-79 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 28, 42, 48, 61, and 74 of copending Application No. 10/344,658. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims encompass the same products. The instant claims and those of the co-pending application encompass transgenic plants and cells that comprise nucleic acid comprising an exogenous vacuolar pyrophosphatase gene. The properties of having increased meristematic activity or

competence, increased biomass, thicker stem structure, increased root structure, increased shoot regeneration capacity, increased root regeneration capacity, are inherent to the instantly claimed products.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 35, 36, 45, 47, 48, 53, 58-76, 59, 68, 69, 75, and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 35: it is unclear what temperature the recitation, "10 0°C" in line 2 is referring to.

In claim 36: the recitation, "chilling temperatures comprises exposure to temperatures below 0°C" renders the claim indefinite. Temperatures of 0°C and below are freezing temperatures, not chilling temperatures.

In claims 44 and 45: it is not clear how the two claims differ from each other, and limit the scope of parent claim 38. Claim 44 indicates that the AVP1 gene or homolog is from a wild type plant. However, the claim from which claim 44 depends indicates that the gene encodes a tonoplast pyrophosphatase, indicating that the gene is from a plant. It is not clear how the limitation of claim 45 differs from that of 44. Claim 45 indicates that the gene is from a transgenic plant. Does this indicate that the gene is the transgene of the transgenic plant? Does

the transgene have to from the transgenic host plant? The metes and bounds of the claims are unclear.

In claims 47, 48, 68, 69, 75, and 76: it is not clear if the seed or progeny comprise the exogenous nucleic acid. It is suggested that the claims be amended to indicate that they do.

In claims 53 and 59: the recitation, "altered phenotypic traits" renders the claims indefinite. It is not clear what traits are encompassed by the recitation, and how they are altered. The metes and bounds of the claim are unclear.

In claim 58: the claim is indefinite because the last step of the method is not consistent with the preamble. Line 1 indicates that the method is for increasing the production of seeds in plants. Part (c) indicates that the fertilized plant is to be cultured until the plant produces mature seeds. However, the recited steps do not indicate that an increased production of seeds has occurred, but rather just that mature seeds have been produced. It is suggested that a recitation be inserted at the end of the claim that indicates that the plant fertilized with the pollen from the transgenic plant produced more seeds when compared to a plant fertilized with pollen from a non-transgenic plant.

In claim 59: the claim broadens the scope of parent claim 58. Claim 59 indicates that altered phenotypic traits are conferred to the transformed plant. As broadly interpreted, these can be any phenotypic traits. However, claim 58 is drawn towards a method for increasing production of seeds in plants. No other change is mentioned in claim 58.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 33-45, 47-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transgenic plants overexpressing AVP1 and having increased tolerance to water deficit and increased NaCl concentrations, does not reasonably provide enablement for transgenic plants having resistance to other types of stresses, or for transgenic plants resistant to externally imposed stresses that are altered in any other way in expression of vacuolar pyrophosphatase, or for increasing the level of expression of vacuolar pyrophosphatase ways other than transgenically expressing an exogenous tonoplast pyrophosphate driven H+ pump gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn towards any transgenic plant that is resistant to any externally imposed stress, said plant comprising a nucleotide sequence comprising an exogenous tonoplast pyrophosphatase drive H+ pump gene operably linked to one or more regulatory elements that result in any alteration in expression of vacuolar pyrophosphatase; or wherein the stresses are water deficit or chilling temperatures; or wherein the exogenous tonoplast pyrophosphatase H+ pump gene encodes AVP1, or a homolog thereof; seed produced from said transgenic plant; progeny of said transgenic plant; any transgenic plant comprising any nucleotide sequence that increases the level of expression of vacuolar pyrophosphatase in any manner; one or more plant cells comprising any exogenous nucleic acid that alters in any manner expression of vacuolar H+ pyrophosphatase in the plant cell;

The specification teaches that *Arabidopsis thaliana* plants were transformed with the coding sequence for the *A. thaliana* vacuolar H+-pyrophosphatase, AVP1, operably linked to a double CaMV 35S promoter. Wild type and transgenic plants were tested for drought tolerance. After 10 days of water deprivation, wild type plants died whereas the transgenic plants survived and continued normal growth (pages 15-16, paragraphs 0061-0063). Growth of wild type and transgenic plants in salty soil was also compared. Plants were placed in soil containing 100 mM NaCl. The NaCl concentration was increased by 100 mM every four days. The transgenic plants were hardier in the salty soil than wild-type plants (pages 17-18, paragraph 0068). Transgenic plants grew well in the presence of 250 mM NaCl for ten days, whereas wild type plants grew poorly and exhibited chlorosis (page 19, paragraph 0072). The specification teaches that enhanced tolerance to salinity and drought in the transgenic plants is most easily explained by an enhanced uptake of toxic cations such as sodium into the vacuole. The increased AVP1 expression presumably provides increased H+ to drive the secondary active uptake of cations into the lumen of the vacuole (pages 19-20, paragraph 0073). Transgenic plants were also shown to have greater calcium uptake than wild type plants (page 20, paragraph 0075).

The specification also teaches that the transgenic AVP1 plants have increased seed yield. Transgenic plants pollinated with wild type pollen produced an average of between about 15 and 20 seeds, with an average seed mass of 2.5 and 3 mg. Wild type plants pollinated with pollen from the transgenic plants produced an average of between about 30 and 35 seeds, with an average seed mass of between about 4 and 5 mg (paragraph 0081). The specification also teaches that seedlings of the transgenic plants have longer root hairs compared to those of wild type seedlings (paragraph 0065).

However, the specification does not teach that vacuolar pyrophosphatase expression was altered in any other manner. The specification does not teach any transgenic plants with increased resistance to any external stresses that have decreased pyrophosphatase expression. As the specification itself teaches that AVP1 expression is increased in the transgenic plants having increased salt and drought tolerance, undue experimentation would be required to alter vacuolar pyrophosphatase expression in any other manner to obtain the same results.

The specification also does not teach any other manner of increasing vacuolar pyrophosphatase expression other than by transgenic expression of a vacuolar H+-pyrophosphatase gene. The specification does not teach any other products that may be used to regulate the expression of vacuolar pyrophosphatase in plant cells, and examples of such regulators are lacking in the prior art. In the absence of further guidance, undue experimentation would be required for one skilled in the art to determine the regulators of expression of vacuolar pyrophosphatases in plant cells and to use genes encoding them to alter expression of vacuolar pyrophosphatase in transgenic plants.

Further, the specification does not teach that the transgenic AVP1 plants displayed any tolerance to chilling temperatures, other any other external stresses other than to salt and drought. The construction of the transgenic AVP1 Arabidopsis plants is also taught in Gaxiola et al. (PNAS, 2001, Vol. 98, pages 11444-11449). While Gaxiola et al. also teach the increased salt and drought tolerance of the transgenic plants, they do not teach increased resistance to any other stresses. Furthermore, the specification does not teach any other phenotypic alterations of the transgenic plants. However, the claims encompass plant cells and plants having any altered phenotypic trait. The specification does not teach what other phenotypic traits are altered in the

transgenic AVP1 plant cells and plants. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. Given the breadth of the claims, unpredictability of the art, and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 33-45, 47-57, 68, 69, and 75-79 are rejected under 35 U.S.C. 102(e) as being anticipated by Gaxiola et al. (U. S. Publication No. 2002/0178464 A1).

The claims are broadly drawn towards any transgenic plant that is resistant to any externally imposed stress, said plant comprising a nucleotide sequence comprising an exogenous tonoplast pyrophosphatase drive H+ pump gene operably linked to one or more regulatory elements that result in any alteration in expression of vacuolar pyrophosphatase; or wherein the stresses are water deficit or chilling temperatures; or wherein the exogenous tonoplast pyrophosphatase H+ pump gene encodes AVP1, or a homolog thereof; seed produced from said transgenic plant; progeny of said transgenic plant; any transgenic plant comprising any

nucleotide sequence that increases the level of expression of vacuolar pyrophosphatase in any manner; one or more plant cells comprising any exogenous nucleic acid that alters in any manner expression of vacuolar H+ pyrophosphatase in the plant cell.

Gaxiola et al. teach transgenic plants, and seeds and progeny derived therefrom, which are tolerant to any salt. The transgenic plants comprise one or more plant cells transformed with exogenous nucleic acid, which can comprise the AVP1 gene, which alters expression of vacuolar pyrophosphatase (paragraphs 0043-0091; claims). The products taught by Gaxiola et al. are the same the instantly claimed products. The properties of resistance to externally imposed stresses, including water deficit and chilling temperatures, and of having increased seed production, when compared to non-transformed plants of the same species, are inherent to the products taught by the reference.

12. Claims 33-45 and 47-83 are rejected. Claim 46 is withdrawn from consideration.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general

nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

September 22, 2003

Ashwin D. Mehta, Ph.D.
Primary Examiner
Art Unit 1638